# **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service** 

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Food and Drug Administration 555 Winderley Place, Suite 200 Maitland, Florida 32751

# VIA FEDERAL EXPRESS

# WARNING LETTER

FLA-99-95

September 24, 1999

#### **FACILITY ID # 112789**

Wayne A. Moccia, M.D. Medical Director Fisherman's Hospital 3301 Overseas Highway Marathon. Florida 33050

Dear Dr. Moccia:

Your facility was inspected August 31, 1999, by a representative of the State of Florida on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

#### Level 1

Phantom Q.C records were missing for 5 weeks for unit 2, General Electric Co. (GE Medical System), Mammo-room.

The specific deficiency noted above appeared on the List of Observations which was issued to your facility on August 31, 1999. This deficiency is symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

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- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, 6601 N.W. 25<sup>th</sup> Street (P.O. Box 592256), Miami, FL 33159-2256, telephone (305) 526-2800, extension 921.

Sincerely,

Douglas D. Tolen

Director, Florida District